DRUG UTILIZATION REVIEW BOARD Meeting Minutes, Open Session July 12, 2006		
DRUG UTILIZATION REVIEW BOARD Meeting Minutes, Open Session EDS/White Lakes Mall Wichita/Kansas City Room Topeka, Kansas July 12, 2006	**Members Present:** Kevin Waite, PharmD; Tom Wilcox, R.Ph.; Brenda Schewe, M.D.; Michael Burke, M.D., Ph.D.; Kevin Kentfield, PharmD; Dennis Grauer, Ph.D; Roger Unruh, D.O. **KHPA Staff Present:** Anne Ferguson R.Ph.; Mary Lesperance, R.Ph.; Nialson Lee R.N.; B.S.N.; Susan Wood R.N.; B.S.N; Wanda Pohl **EDS Staff Present:** Debra Quintanilla, R.N.; Lisa Todd, R.Ph.; Karen Kluczykowski, R.Ph.	**Representatives:** Christi Davis O'Brien (Amylin); Amy Blickensderfer (Amylin); Marty Mazurek (Merck); Richard Mesquias (Eli Lilly and Company); Cheryl Snyder (Cottton O'Neil Diabetes Center); Marcia Wright (Pfizer); Jacque Marinac (Pfizer); Jim Baumann (Pfizer), Ameen Ghannam (Pfizer), Joe Summers (TAP); Barbara Belcher (Merck); Jeff Knappen (Allergan); Bud Burke (Eli Lilly); Mike Huffles (Huffles Government Relations); Bill Gittner (Pfizer); Mike Larkin (KS Pharmacists Association); Jeremy Vander Voort (KS Pharmacists Association); Paul Fung (FirstGuard Health Plan), Joe Summers (TAP),
TOPIC	**DISCUSSION**	**DECISION AND/OR ACTION**
I. Call to Order	The Meeting was called to order by Dr. Burke, Chair, at 10 a.m.	
II. Announcements	• Anne announced the appointment of Judy McDaniel Dowd, PA-C. She will fill the vacant position on the DUR Board requiring an ARNP or PA. Ms. Dowd will attend the September meeting. • Nialson Lee announced the transition of the department from the Division of Health Policy and Finance to the Kansas Health Policy Authority (KHPA). He also announced the resignation of Bob Day, and the appointment of Marcia Nielsen, Ph.D., M.P.H., as Executive Director of the Authority.	

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III. Review and Approval of May 10, 2006 Meeting Minutes	• Dr. Unruh requested a correction on page 5 to read "Anne proposed the removal of PA requirement for Celebrex and the criteria *are* to remain…"	• A motion was made by Dr. Unruh to approve the minutes with the proposed correction and was seconded by Dr. Grauer. The motion carried unanimously by roll call.
IV. New Business A. Byetta® (exenatide injection) 1. Review Prior Authorization Criteria	• Anne presented information to the Board about Byetta® and reviewed the proposed Prior Authorization (PA) criteria. Anne is requesting the Board make recommendations on age restrictions, blood glucose monitoring, and the length of PA approvals. • Dr. Kentfield asked if the requirement that HbA1c be $\geq$ 7 % was from the package insert. • Anne stated yes and from current American Diabetes Association (ADA) guidelines. • Dr. Burke inquired as to where in the package labeling it refers to an age restriction. • Anne pointed out in the packaging labeling that safety and effectiveness has not been established in pediatrics patients.. • Dr. Kentfield asked how blood glucose testing would be monitored if required as part of the criteria. • Anne stated it would be a question posed to the physician at the time the PA is requested, i.e. is the patient capable of and compliant with blood glucose testing.	
2. Public Comment (5 minutes)	• Amy Blickensderfer (Amylin) presented information to the Board	

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IV. New Business A. Byetta® (exenatide injection) continued 3. DUR Board /Discussion Recommendation	about Byetta® • Dr. Burke recommended adding the age restriction of 18 or older and taking Dr.Blickensderfer's recommendation to add and/or to #2of the criteria. He pointed out that because the American Academy of Endocrinologists is recommending A1c below 6.5%, we may want to consider changing the criteria to reflect this. • Discussion surrounded the requirement to monitor blood glucose levels as stated in criteria #4. • Dr. Schewe would like to make blood glucose monitoring a recommendation as opposed to a requirement for PA approval. • Dr. Waite would like the PA criteria to match the current recommendations of the ADA in regards to A1c testing, and to require A1c testing every 6 months. • Dr.Grauer questioned whether the renewal criteria should read "HbA1c lowering from pretreatment levels" as patients already receiving medication may not be able to get the PA renewed if their levels reach $\leq$ 6.5%. • Dr. Waite suggests it to read "or achievement of therapy goals". Dr. Burke would like #2 to read "Pretreatment documented …"	• A motion was made by Dr. Waite to approve the proposed PA criteria with the following changes : #1. Add age criteria to read "Patient must be at least 18 years old". #2. Pt. must have diagnosis of type 2 diabetes. #3. Add "Pretreatment" to the beginning of the sentence; decrease HbA1c to $\geq$ 6.5%; add "and/or" between a and b. #4. Reword to read "Adjunct use with metformin and/or sulfonylurea". Add recommendations section to read "Patient should be monitoring blood glucose levels routinely. When used as adjunct therapy with a sulfonylurea, a reduction in the dose of sulfonylurea should be considered". Allow approval for 6 months, and allow renewal if achievement of therapy goals has been reached. Dr. Kentfield seconded the motion. The motion carried unanimously by roll call.

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3. DUR Board /Discussion Recommendation	• Dr. Kentfield would like consideration of lowering the dose of sulfonylurea to be included as a recommendation. • With no further Board discussion, a motion was placed before the Board.	
B. Symlin® (Pramlintide) 1. Review Prior Authorization Criteria 2. Public Comment (5 minutes) 3. DUR Board/Discussion Recommendation	• Anne presented information about Symlin® and reviewed the proposed PA criteria. Anne pointed out specific patient selection criteria as noted in the package labeling. • Amy Blinkensderfer (Amylin) presented information about Symlin® and asked the Board if they are seeing a utilization pattern that would necessitate PA. • Anne responded that utilization is low, but the issue surrounding Symlin® is safe prescribing and appropriate patient selection. • Dr. Blindensderfer stated that the company is promoting the use of this drug in patients 15 and older. • Dr. Burke stated we would need documentation/data from Amylin in order to change our criteria. • Dr. Grauer pointed out the package labeling states this drug hasn't been studied in pediatric patients. • Dr. Grauer asked if we know which providers are prescribing the medication. • Anne responded that she can obtain this information for the next meeting. • Dr. Burke pointed out that the amount of utilization is not the only issue with	• A motion was made by Dr. Schewe to accept the PA criteria with the following changes: #3 Documented inadequate postprandial glycemic control …, move #5 to a recommendation to read, "Patient should perform frequent pre-and post-meal glucose monitoring. An initial 50% reduction in pre-meal doses of short- acting insulin is recommended." Approvals will be for 6 months. Renewals will be based on documented improvement to postprandial glycemic control. The motion was seconded by Dr. Unruh. The motion carried unanimously by roll call.

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B. Symlin® (Pramlintide) 3. DUR Board/Discussion Recommendation	this drug; there is a boxed warning and safety considerations. PA allows the Board to track utilization more closely. • Dr. Waite agrees that for providers that are prescribing appropriately, the criteria will be met and PA approved. • Dr. Burke suggested removing the requirement of A1c from the criteria, as recommended by Dr. Blickensderfer, and to focus on postprandial glycemic control. • Dr. Burke recommends the following wording "documented inadequate postprandial glycemic control with current mealtime therapy". • Dr. Schewe suggests we add recommendations to the criteria which address blood glucose monitoring. • Dr. Burke would like to include a recommendation to decrease mealtime insulin as stated in the package labeling. • Dr. Schewe recommends the following wording for renewals, "renewals will be approved based on documented improvement to postprandial glycemic control, …" • The Board would like to revisit utilization in 6 months. • With no further Board discussion, a motion was placed before the Board.	

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C. Exubera® (insulin human [rDNA orgin] inhalation powder) 1. Review Prior Authorization Criteria	• Anne presented information about Exubera®. Anne handed out reimbursement information and a revised PA proposal. The proposed PA draft was reviewed. There are specific patient selection criteria to consider when prescribing this medication. Anne requested that the Board make a recommendation as to whether or not this drug should be placed on PA. If PA is recommended, the proposed PA criteria need to be modified in the following areas: Exclusion of patients with COPD and Asthma, and blood glucose monitoring requirement.	• A motion was made by Dr. Grauer to table the topic until 3 to 6 months of utilization data can be obtained to include Diagnosis of patient (Type I vs. Type II), and SQ insulin usage. The motion was seconded by Dr. Unruh. The motion carried by roll call with all voting yes except Dr. Waite who recused himself from the vote.
2. Public Comment (5 minutes)	• Ameen Ghannam and Jim Baumann (Pfizer) presented information to the Board about Exubera®. • In response to Pfizer stating that only 210 patients will initially be exposed to Exubera®, Anne asked if non-detailed physicians can prescribe this medication and will it be available at the local pharmacy.	
3. DUR Board /Discussion Recommendation	• Dr. Baumann stated that non- targeted physicians can prescribe (although not encouraged to) and it will be available at local pharmacies. • Anne asked if there will be direct to consumer advertising. • Dr. Ghannam stated not for the first year as directed by the FDA, and that they will also be doing post marketing surveillance for seven years.	

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C. Exubera® continued 3. DUR Board /Discussion Recommendation	• Dr.Unruh asked if endocrinologists would be selected for the special education. • The Pfizer representative stated most would be endocrinologists. • Cheryl Snyder, RNCDE Cotton O'Neil Diabetes Center, provided insight into her challenge to start patients on injectable insulin. She is presently involved in a clinical research trial with inhaled insulin for another company. • Dr. Grauer asked if she is seeing any difference between types I or II in her practice. • Ms. Snyder stated that her study is for Type I, and the response to inhaled insulin has been interesting. She has screened 7 people for the study and only 2 wanted to randomize for the inhaled insulin. • Anne asked Pfizer what the significance is of the development of antibodies when exposed to this drug. • Dr. Ghannam stated that there is an increase in antibodies probably due to delivery to the lung, and the antibody levels declined over time after discontinuation. They did not decline back to baseline over the two year follow-up period, and the development of antibodies was more significant in Type 1 patients vs. Type II. • Dr. Schewe asked if this drug should be considered for the PDL. • Anne stated it was possible as an	

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C. Exubera® continued 3. DUR Board /Discussion Recommendation	alternative delivery device, but the safety issues might not be addressed through the PDL process if the drug had preferred status. • Anne would like the Board to determine if we should require PA for this drug. • Dr. Burke questioned if PA criteria has been written prior to utilization data being available. • Anne stated that we have with previous drugs due to the length of time it takes to implement a PA in the system. • Dr. Grauer asked if we want patients to fail before they have this medication. • Drs. Burke and Schewe agree that we probably don't want a statement requiring failure, but recommend lack of efficacy, inadequate response, treatment failure, etc. • Dr. Schewe feels that there are subsets of patients that may benefit from this inhaled form of insulin as first line therapy due to their fears of injection. • Dr. Burke feels that the proposed PA criteria would require some changes if it is decided that the drug should require PA. • Dr. Waite recused himself from the discussion and vote due to his association and history with the Cotton O'Neil Diabetic Learning Center. • Dr. Unruh asked how much residual	

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C. Exubera® continued 3. DUR Board /Discussion Recommendation	• drug in the mouth becomes bioavailable, and what percent of inhaled dose is bioavailable. • Dr. Ghannam stated that 15% of the inhaled dose is bioavailable, and residual drug outside of the lung is enzymatically degraded or ingested and does not have any insulin effect. • Dr. Kentfield was surprised that only 2 out of 7 patients preferred to use the inhaled form and feels we should table until utilization can be reviewed in 3- 6 • Dr. Grauer would like to know how many Type I and Type II patients are using Exubera® and if they are using SQ insulin as well. • Mr. Wilcox questioned Pfizer on what they consider to be their cost competitor. • Jim Baumann stated Avandia® and Actos®. Their cost compared to Exubera® is considered cost neutral. • Mary stated this may not be the case since these drugs are on the PDL and the net cost to the state may be lower. • With no further Board discussion, a motion was placed before the Board.	

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D. Suboxone®/Subutex® (buprenophine/naloxone) 1. Review Prior Authorization Criteria 2. Public Comment (5 minutes)	• Anne presented information about Suboxone® and Subutex® including a review of the proposed PA criteria. Some beneficiaries are receiving these drugs in addition to narcotics from different providers during the same time period. Two beneficiaries are getting the prescriptions from out-of-state non-Medicaid providers. Some beneficiaries are receiving high doses of the drugs and do not appear to have appropriate diagnosis listed on their profiles. • Anne invited Dr. Jan Campbell with the V.A. to address the Board and answer questions on this topic. Dr. Campbell felt the issue of short acting narcotics plus Suboxone® speaks of diversion unless the patient had just encountered a surgical procedure. She also recommends a daily limit of 40mg per day due to the ceiling effect of Suboxone®. She does not think access to certified providers in Kansas is an issue anymore, and she encourages the lock-in requirement to allow for coordination of care. • Dr. Burke asked for clarification in regards to pain treatment recommendations and should we be treating differently. • Dr. Campbell encourages aggressive treatment of pain, but prescribers must	• A motion was made by Mr. Wilcox to accept the modified PA criteria to read: 1. Patient must have a diagnosis of opioid dependence. 2. Patient must be actively involved in addiction treatment. 3. Qualified Prescribing provider (under Drug Addiction Treatment Act of 2000) must provide confirmation of their waiver from SAMHSA. 4. Prescribing provider must practice in Kansas or border city and be a Kansas Medicaid Provider. 5. Beneficiary will be placed in lock-in. Lock-in Providers will include the Pharmacy and Primary Care Provider. 6. Daily dosing not to exceed 40mg. Dr. Schewe seconded the motion. The motion carried unanimously by roll call.

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D. Suboxone®/Subutex® (buprenophine/naloxone	be alert to the risk factors for addiction. • Dr.Burke restated that once the patient starts on Suboxone® that is their narcotic. • Dr. Campbell verified this. • Dr. Burke questioned taper vs. maintaining addictions. • Dr. Campbell responded that tapering is a long process that is worthwhile for people without typical addiction history. There is still a subset of patients that will relapse if tapered off the Suboxone®. These patients require maintenance therapy. • Dr. Burke asked Dr. Campbell to address the high dose issue we have seen in some of our patients. He pointed out the package insert recommends 16-24mg daily. • Dr. Campbell recommends 40mg daily which should take care of 90% of the patients. Patients transitioning from Methadone to Suboxone® require the 40mg dose initially. Although, not many patients make the transition due to difficulty in tapering down to 60mg of Methadone prior to converting to Suboxone®. • Mary stated that the limit needs to be set high enough to treat a majority of patients,so the PA is not denied inappropriately. • Dr. Campbell responded that 40mg	

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D. Suboxone®/Subutex® (buprenophine/naloxone DUR Board/Discussion Recommendation	would be appropriate and to use the appeal process for doses above 40mg. • Dr. Burke thanked Dr. Campbell for speaking to the Board. • Dr. Burke would like to recommend changing the wording of #1 to allow for maintenance treatment. He thinks the patients need to be involved in addiction treatment. • Nialson recommended adding Border Cities that are Medicaid Providers to the allowed prescribers. • Dr. Burke recommends specifying that beneficiary would be locked in to a Primary Care Physician and a Pharmacy. • Dr. Burke would like to see a bullet to limit daily dose to 40mg. • With no further discussion, a motion was placed before the Board.	
E. Promethazine-age restriction 1. Review KHPA proposal 2. Public Comment (5 minutes) 3. DUR Board/Discussion Recommendation	• Anne presented information about the recent FDA warnings addressing use of promethazine in children under age two. KHPA would like to propose an edit that would deny promethazine claims for children under age two. • No public comment. • With no Board discussion a motion was placed before the Board	• A motion was made by Dr. Unruh to approve the edit to require patient receiving promethazine be 2 years of age or older and seconded by Dr. Waite. The motion carried unanimously by roll call.

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F. Ultracet® (tramadol/Actaminophen 1. Review proposed limitations 2. Public Comment (5 minutes) 3. DUR Board Recommendation	• Anne presented the KHPA proposal to limit tramadol/acetaminophen to 40 units/31 day based on package labeling. • No public comment. • Dr. Burke clarified that tramadol does not have the limitation on duration of therapy as does the combination drug. • Anne stated that currently tramadol has a daily limit of 400mg. There is an edit in the system that monitors for this limit. The combination product currently has a 40 tablet limit per 5 days but not a monthly limit. Beneficiaries can fill 40 tablets every 5 days continuously. • It was determined that the combination product is available in generic form. • With no further Board discussion, a motion was placed before the Board.	• A motion was made by Dr. Wilcox to approve the proposed limit for tramadol/acetaminophen to 40 tablets in 31 days and seconded by Dr. Kentfield. The motion carried unanimously by roll call.
G. Adjourn Open Meeting	• Meeting adjourned at 12:30.	• A motion to adjourn the meeting was made by Dr. Schewe and seconded by Dr. Unruh. The motion carried unanimously by roll call.